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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 09/943,054   | 08/30/2001  | Seiichi Araki        | 109536-161          | 8743             |
| 23483  | 7590        | 07/09/2007           | EXAMINER            |                  |
| WILMER CUTLER PICKERING HALE AND DORR LLP<br>60 STATE STREET<br>BOSTON, MA 02109 |             |                      | ANDERSON, JAMES D   |                  |
| ART UNIT   |             | PAPER NUMBER         |                     |                  |
| 1614   |             |                      |                     |                  |
| NOTIFICATION DATE  |             | DELIVERY MODE        |                     |                  |
| 07/09/2007   |             | ELECTRONIC           |                     |                  |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

michael.mathewson@wilmerhale.com  
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|                              |                               |                  |
|------------------------------|-------------------------------|------------------|
| <b>Office Action Summary</b> | Application No.               | Applicant(s)     |
|                              | 09/943,054                    | ARAKI ET AL.     |
|                              | Examiner<br>James D. Anderson | Art Unit<br>1614 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on 01 June 2007.
- 2a) This action is **FINAL**.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 1,3-6,8,9 and 58-62 is/are pending in the application.
- 4a) Of the above claim(s) 59-62 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1,3-6,8,9 and 58 is/are rejected.
- 7) Claim(s) 1,3-6,8 and 9 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. 08/420,632.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

|  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**CLAIMS 1, 3-6, 8-9 & 58-62 ARE PRESENTED FOR EXAMINATION**

Applicants' amendment filed 6/1/2007 has been received and entered into the application.

Accordingly, claims 1, 3-6, 8 and 9 have been amended, claims 2, 7 and 10-57 have been cancelled and claims 58-62 have been added.

The amendments and Applicants' remarks have overcome the rejections not reiterated herein from the previous office action. Such rejections are hereby withdrawn. The following rejections are either reiterated or newly applied and constitute the totality of issues remaining in the present application.

***Election/Restrictions***

Newly submitted claims 59-62 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the claims recite a method of enhancing the immune response to a virus comprising administering a composition comprising at least one of riboflavin, flavin mononucleotide and flavin adenine dinucleotide and the inactivated virus. The originally presented claims are drawn to methods comprising administering riboflavin, flavin mononucleotide and flavin adenine dinucleotide or treat an *E. coli* infection (a bacterial infection).

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 59-62 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR § 1.142(b) and MPEP § 821.03.

***Defective Oath***

The reissue oath/declaration filed with this application is defective (see 37 CFR § 1.175 and MPEP § 1414) because of the following: 1) the subject matter of amended claims 1, 3-6 and 8-9, drawn to a method of enhancing the immune response to infection by *E. coli*, was not identified as an error in the originally filed oath/declaration; 2) the subject matter of newly added claim 58, drawn to the method of claim 1 further comprising glutamine and proline, was not identified as an error in the originally filed oath/declaration; and 3) the subject matter of newly added claims 59-62, drawn to a method of enhancing the immune response to a virus or increasing the survival rate of a human susceptible to infection with a virus comprising administering a riboflavin and the inactivated virus, were not identified as errors in the originally filed oath/declaration.

Examiner notes that the errors identified in the oath/declaration are not sufficient to specifically identify errors in the claims. For example, merely stating a "...failure to include a claim directed to..." is not considered a sufficient error statement since Applicants have not pointed out what the other claims lacked that the newly added or amended claims have, or *vice versa*. Please see M.P.E.P. § 1414(II)(C).

A supplemental oath/declaration is required:

Please note that if a reissuable error is not given by allowance the case may not meet the criteria for reissue. To advance prosecution, it would be helpful if Applicants were to submit a supplemental Oath/Declaration that identifies a specific error correctable by reissue.

***Claim Rejections - 35 USC § 251***

Claims 1, 3-6, 8-9 and 58 are rejected as being based upon a defective reissue Oath/Declaration under 35 U.S.C. § 251 as set forth above. See 37 CFR § 1.175. The nature of the defect(s) in the Oath/Declaration is set forth in the discussion above in this Office action.

***Application Objections***

This application is objected to under 37 CFR § 1.172(a) as the assignee has not established its ownership interest in the patent for which reissue is being requested. An assignee must establish its ownership interest *in order to support the consent to a reissue application required by 37 CFR 1.172(a)*. The submission establishing the ownership interest of the assignee is informal. There is no indication of record that the party who signed the submission is an appropriate party to sign on behalf of the assignee. 37 CFR § 3.73(b).

A proper submission establishing ownership interest in the patent, pursuant to 37 CFR § 1.172(a), is required in response to this action.

The person who signed the submission establishing ownership interest has failed to state his/her capacity to sign for the corporation or other business entity, and he/she has not been established as being authorized to act on behalf of the assignee, *e.g.* the Title of the person signing was left blank. See MPEP § 324.

Similarly, the Consent of Assignee, filed 4/15/2002 is objected to because the title of the person signing on behalf of the assignee was left blank.

***Claim Objections***

Claims 1, 3-6 and 8-9 are objected to because of the following informalities: the amended original claims are not in the proper format (e.g., matter to be omitted from original claims must be enclosed in brackets). Please see 37 C.F.R. 1.173. Appropriate correction is required.

**§ 1.173 Reissue specification, drawings, and amendments.**

(1) Specification, including claims. The entire specification, including the claims, of the patent for which reissue is requested must be furnished in the form of a copy of the printed patent, in double column format, each page on only one side of a single sheet of paper. If an amendment of the reissue application is to be included, it must be made pursuant to paragraph (b) of this section.

(b) Making amendments in a reissue application. An amendment in a reissue application is made either by physically incorporating the changes into the specification when the application is filed, or by a separate amendment paper. If amendment is made by incorporation, markings pursuant to paragraph (d) of this section must be used.

(d) Changes shown by markings. Any changes relative to the patent being reissued which are made to the specification, including the claims, upon filing, or by an amendment paper in the reissue application, must include the following markings:

- (1) **The matter to be omitted by reissue must be enclosed in brackets;** and
- (2) The matter to be added by reissue must be underlined, except for amendments submitted on compact discs (§§ 1.96 and 1.821(c)).

Claim 1 is objected to because of the following informalities: the word “pharmalogically” is misspelled in line 4. The correct spelling is ---pharmacologically---. Appropriate correction is required.

Claim 6 is objected to because of the following informalities: the word “methy” is misspelled in line 5. The correct spelling is ---methyl---. The word “chondroitinn” is misspelled in line 6. The correct spelling is ---chondroitin---. The word “faty” is misspelled in line 6. The correct spelling is ---fatty---. Appropriate correction is required.

***Conclusion***

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James D. Anderson whose telephone number is 571-272-9038. The examiner can normally be reached on MON-FRI 9:00 am - 5:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

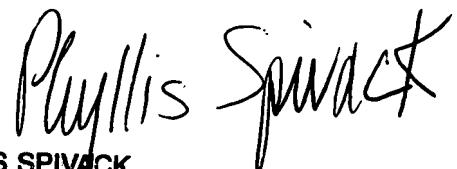
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



James D. Anderson  
Patent Examiner  
AU 1614

June 27, 2007



PHYLLIS SPIVACK  
PRIMARY EXAMINER